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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,551	01/15/2004	Orhun K. Muratoglu	37697-0085	3038

61263 7590 05/30/2006

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EXAMINER	
STAICOVICI, STEFAN	

ART UNIT	PAPER NUMBER
1732	

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/757,551	MURATOGLU ET AL.	
	Examiner	Art Unit	
	Stefan Staicovici	1732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-77 and 80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-77, 80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/7/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 21, 2006 has been entered.

Response to Amendment

2. Applicants' amendment filed April 21, 2006 has been entered. Claims 1-77 and 80 are pending in the instant application.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-77 and 80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 1, 34, 41, 48, 55, 62 and 77, it is not clear whether the "oxidation and wear resistant medical implant" in the preamble is the same or different than the "oxidation and wear resistant medical implant" limitation on the last line of each of claims 1, 34, 41, 48, 55, 62 and 77. Further clarification is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-2, 5-19, 21-35, 38-42, 45-49, 52-55, 57, 59-62, 64-72 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren *et al.* (US Patent No. 6,448,315) in view of Hahn (US Patent No. 5,827,904).

Lidgren *et al.* ('315) teach the basic process for making a medical implant including, providing UHMWPE powder, mixing said powder with vitamin E (antioxidant) to reduce oxidation, irradiating said mixture with radiation, compression molding said irradiated mixture into said medical implant or machining medical implants from compression molded blocks of said irradiated mixture, packaging said medical implant and sterilizing said package (see col. 4, line 45 through col. 5, line 10 and col. 5, line 66 through col. 6, line 8). Further, it is submitted that Lidgren *et al.* ('315) teach reducing the free radicals and irradiating said mixture to cross-link the PE chains, hence controlling the amount of free radicals by irradiation and antioxidant amount. It is noted that a medical implant must be oxidation and wear resistant in order to function as described. The purpose of vitamin E is to create an oxidation resistant product, hence it is submitted that the medical implant of Lidgren *et al.* ('315) is oxidation resistant in order to function as described. The purpose of using UHMWPE, which has large molecular weight, is to create a product that is wear resistant, hence it is submitted that the medical implant of Lidgren

et al. ('315) is oxidation resistant in order to function as described.

Regarding claims 1, 34-35, 41-42, 48-49, 55, 62 and 77, although Lidgren *et al.* ('315) teach doping a polymeric material (powder) with an antioxidant (vitamin E), Lidgren *et al.* ('315) do not teach doping a consolidated polymeric material with an antioxidant by diffusion. Hahn ('904) teaches a process for making a medical implant by either consolidating a polymeric material (UHMWPE) and doping said consolidated polymeric material with an antioxidant or as an equivalent alternative, doping said polymeric material and then consolidating said doped, polymeric material (see col. 3, lines 15-20 and col. 7, lines 24-47). Hahn ('904) teaches that both methods provide for antioxidant material to be present in the final, consolidated product. Further, Hahn ('904) teaches soaking said consolidated polymeric material in an antioxidant solution such that the soaking time, temperature and solution strength determine the doping level (see col. 3, lines 29-35). Therefore, it would have been obvious for one of ordinary skill in the art to have doped a consolidated polymeric material as an equivalent alternative to doping the polymeric material as taught by Hahn ('904) in the process of Lidgren *et al.* ('315) because, Hahn ('904) teaches that such process step sequences are equivalent alternatives and also because both references teach the same polymeric material, UHMWPE, and the same end-product (medical implant).

In regard to claims 5-7, 38-40, 45-47, 52-54, 59-61 and 65-67, Hahn ('904) teaches soaking said consolidated polymeric material in an antioxidant solution such that the soaking time, temperature and solution strength determine the doping level (see col. 3, lines 29-35). Hence, it is submitted that soaking time, temperature and solution strength are result-effective

variables. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). Therefore, it would have been obvious for one of ordinary skill in the art to have doped a consolidated polymeric material as an equivalent alternative to doping the polymeric material as taught by Hahn ('904) in the process of Lidgren *et al.* ('315) because, Hahn ('904) specifically teaches that such process step sequences are equivalent alternatives and also because both references teach the same polymeric material, UHMWPE, and the same end-product (medical implant).

Specifically regarding claims 8 and 68, Lidgren *et al.* ('315) teach annealing at a temperature above the melting temperature of the consolidated polymeric material (see col. 6, lines 8-18).

Regarding claims 9-10, 12, 30-31, 69-70 and 72, Lidgren *et al.* ('315) teach UHMWPE (polyolefin) powder and an antioxidant (vitamin E, alpha-tocopherol) (see Abstract).

In regard to claims 11 and 71, Lidgren *et al.* ('315) teach a medical implant for a joint replacement, specifically a femoral component (see col. 1, lines 13-16 and 50-55).

Specifically regarding claims 13-19, 21-26, 57 and 64, Lidgren *et al.* ('315) teach gamma radiation of 3.3-100 Mrad in air and an inert atmosphere, *i.e.* nitrogen gas (fluid) and, remelting the irradiated polymer in a non-oxidative atmosphere, *i.e.* inert or vacuum (1% oxygen) to reduce the free radicals (see col. 2, lines 13-55).

Regarding claim 27, Lidgren *et al.* ('315) teach the use of a solvent (ethanol) (see col. 3, lines 10-15).

In regard to claims 28-29, Lidgren *et al.* ('315) teach diffusion of an antioxidant in a supercritical fluid such as, CO_2 (see col. 4, lines 62-65).

Specifically regarding claims 32-33, it is noted that the limitation are functional limitations. In a claim drawn to a process of making, it is the structure that carries patentability and not the functional limitation. Therefore, it would have been obvious for one of ordinary skill in the art to have made a non-permanent medical device, such as a tubing using the process of Lidgren *et al.* ('315) in view of Hahn ('904) because, Lidgren *et al.* ('315) teaches that the doped UHMWPE provides for improved properties that enhance the material's use a biological material, hence providing for an improved product such as a catheter or a non-permanent medical device.

7. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren *et al.* (US Patent No. 6,448,315) in view of Hahn (US Patent No. 5,827,904) and in further view of Parth *et al.* (2002) (referenced as A11 in the IDS filed 7/16/2004).

Lidgren *et al.* ('315) in view of Hahn ('904) teach the basic claimed process as described above.

Regarding claim 20, although Lidgren *et al.* ('315) in view of Hahn ('904) teach treating UHMWPE with gamma radiation, Lidgren *et al.* ('315) in view of Hahn ('904) do not teach e-beam radiation. However, the use of e-beam radiation as an equivalent alternative to gamma radiation (see Abstract and Conclusions) is well known as evidenced by Parth *et al.* (2002). Therefore, it would have been obvious for one of ordinary skill to have used e-beam radiation as an equivalent alternative to gamma radiation as taught by Parth *et al.* (2002) to treat UHMWPE in the process of Lidgren *et al.* ('315) in view of Hahn ('904) because, Parth *et al.* (2002) specifically teach the use of e-beam radiation as an equivalent alternative to gamma radiation and

also because all references teach similar materials and end-products.

8. Claims 3-4, 36-37, 43-44, 50-51, 56, 58, 63 and 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren et al. (US Patent No. 6,448,315) in view of Hahn (US Patent No. 5,827,904) and in further view of Burstein *et al.* (US Patent No. 6,620,198).

Lidgren *et al.* ('315) in view of Hahn ('904) teach the basic claimed process as described above.

Regarding claims 3-4, 36-37, 43-44, 50-51, 56, 58, 63, 73-75, although Lidgren *et al.* ('315) teach a metallic/UHMWPE component (see col. 1, lines 14-20), Lidgren *et al.* ('315) in view of Hahn ('904) do not teach compression molding a metallic/UHMWPE component. Burstein *et al.* ('198) teach compression molding a polymer element (140) (UHMWPE) and a metallic element (130) to form a medical component (see col. 5, lines 1-10). It is submitted that a metallic/UHMWPE component includes a metal/polymer interface. Therefore, it would have been obvious for one of ordinary skill in the art to have compression molded a polymer element and a metallic element as taught by Burstein *et al.* ('198) to form a medical component by the process of Lidgren *et al.* ('315) because, Burstein *et al.* ('198) teach that a metallic/polymer interface provides for an improved product having improved biological properties and also because Lidgren *et al.* ('315) teach a metallic/UHMWPE component (see col. 1, lines 14-20), hence teaching the desirability of a metallic/polymer interface.

9. Claims 76 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren et al. (US Patent No. 6,448,315) in view of Hahn (US Patent No. 5,827,904) and in further view of Burstein *et al.* (US Patent No. 6,620,198) and Ylanen *et al.* (US Patent No. 6,517,857 B2).

Lidgren *et al.* ('315) in view of Hahn ('904) and in further view of Burstein *et al.* ('198) teach the basic claimed process as described above.

Regarding claims 76 and 80, although Lidgren *et al.* ('315) teach a metallic/UHMWPE component (see col. 1, lines 14-20), Lidgren *et al.* ('315) in view of Hahn ('904) and in further view of Burstein *et al.* ('198) do not teach compression molding a metallic/ceramic component. Ylanen *et al.* ('857) teach that polymers, metals and ceramic are all alternative materials for making a medical component. Therefore, it would have been obvious for one of ordinary skill in the art to have compression molded a ceramic element (non-metallic) and a metallic element to form a ceramic/metallic interface by the process of Lidgren *et al.* ('315) in view of Hahn ('904) and in further view of Burstein *et al.* ('198) and Ylanen *et al.* ('857) because, Ylanen *et al.* ('857) specifically teach that polymers, metals and ceramic are all alternative materials for making a medical component, whereas Lidgren *et al.* ('315) teach a medical component.

Response to Arguments

10. Applicants' remarks filed April 21, 2006 have been considered.

11. Applicants argue that "Applicants methodologies (i) allow for a gradient of antioxidant in the consolidated material while (ii) minimizing thermal degradation of the antioxidant and (iii) yellowing of the material that includes the antioxidant during consolidation" (see amendment filed 4/21/06 at 13). However, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification,

limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

12. Applicants argue that the advantages of the claimed invention "cannot be achieved via melting of cross-linked polymer" as presented in the prior art (see amendment filed 4/21/06 at 13). In response, it is noted that whether the "cross-linked polymer" is melted or not melted is not a disputed limitation. Further, the transitional term "comprising" is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004).

13. Applicants argue that the advantages of the claimed invention "cannot be achieved via... doping of unconsolidated polymer" as presented in the prior art (see amendment filed 4/21/06 at 13). In response, it is noted that Hahn ('904) specifically teaches a process for making a medical implant by either consolidating a polymeric material (UHMWPE) and doping said consolidated polymeric material with an antioxidant or as an equivalent alternative, doping said polymeric material and then consolidating said doped, polymeric material (see col. 3, lines 15-20 and col. 7, lines 24-47). Hahn ('904) teaches that both methods provide for antioxidant material to be present in the final, consolidated product, hence teaching doping of a consolidated polymer.

Response to Declaration of Orhun Muratoglu, PhD

14. The Declaration under 37 CFR 1.132 filed April 21, 2006 has been considered but is insufficient because "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." MPEP §716.02(d).

The claimed invention is drawn to a process of making a medical implant, including providing or forming a consolidated polymeric material, followed by, a step of irradiation, a step of machining and a step of doping, performed in various sequences as shown below:

Claims 1 and 77: irradiating, machining and doping;

Claim 34: machining, irradiating and doping;

Claim 41: doping, machining and irradiating;

Claim 48: doping, irradiating and machining;

Claim 55: machining; doping and irradiating;

It is noted that the process of Lidgren *et al.* ('315) in view of Hahn ('904) teaches a step of doping followed by either, machining and irradiating, irradiating and machining or irradiating because, Hahn ('904) teaches doping a consolidated material, whereas Lidgren *et al.* ('315) teach machining and irradiating a doped, consolidated polymeric material. MPEP §2144(IV)(C) states that the "selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results." (Emphasis added). See In re Burhans, 154 F.2d 690, 69 USPQ 330 (CCPA 1946). Therefore, it is submitted that in order for the "objective evidence" to be commensurate in scope with the claims, Applicants are required to show "new or unexpected results" resulting from the specifically claimed sequences of the irradiating, machining and doping process steps. Hence, it is submitted that the provided evidence is not "commensurate in scope with the claims which the evidence is offered to support" and as such, Applicants have not provided "factual evidence" as required under MPEP §716.01(c).

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stefan Staicovici, Ph.D. whose telephone number is (571) 272-1208. The examiner can normally be reached on Monday-Friday 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson, can be reached on (571) 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stefan Staicovici, PhD

Stefan Staicovici

Primary Examiner 5/26/06

AU 1732

May 26, 2006